Notice of Allowability	Application No.	Applicant(s)	
	10/813,336	GRIMES ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment after Non-Final Rejection, filed 3/3/06*.

2. ☒ The allowed claim(s) is/are *18, 90-94, 26, 95-96, 30, 97-101, 81, and 102-103 (renumbered as 1-18, respectively)*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 3/3/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *041406* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Algis Anilionis on April 14, 2006.

The application has been amended as follows:

Specification:

On p. 17-18, the paragraph beginning "DEPOSIT of HYBRIDOMA CELL LINES" has been replaced with the following replacement paragraph:

--DEPOSIT OF HYBRIDOMA CELL LINES

The following hybridomas that produce particular MAbs of the present invention were deposited with the American Type Culture Collection (ATCC, Manassas, VA) on March 25, 2004:

1. Hybridoma 400-1 produces MAb 400-1 that selectively binds an N-terminal epitope of G17 or Gly-extended G17 and is assigned accession number PTA-5889.

2. Hybridoma 400-2 produces MAb 400-2 that selectively binds an N-terminal epitope of G17 or Gly-extended G17 and is assigned accession number PTA-5890.

3. Hybridoma 400-3 produces MAb 400-3 that selectively binds an N-terminal epitope of G17 or Gly-extended G17 and is assigned accession number PTA-5891.

4. Hybridoma 400-4 produces MAb 400-4 that selectively binds an N-terminal epitope of G17 or Gly-extended G17 and is assigned accession number PTA-5892.

5. Hybridoma 401-2 produces MAb 401-2 that selectively binds an N-terminal epitope of G34 or Glycine-extended G34 and is assigned accession number PTA-5893.

6. Hybridoma 445-1 produces MAb 445-1 that selectively binds a C-terminal epitope of Glycine-extended G17 or Glycine-extended G34 and is assigned accession number PTA-5894.

7. Hybridoma 445-2 produces MAb 445-2 that selectively binds a C-terminal epitope of Glycine-extended G17 or Glycine-extended G34 and is assigned accession number PTA-5895.

8. Hybridoma 458-1 produces MAb 458-1 that selectively binds a C-terminal epitope of G17 or G34 and is assigned accession number PTA-5896.--

Claims:

Claims 14-17, 19-25, 27-29, 31-37, and 82-89 have been canceled without prejudice.

New claims 90-103 have been added as detailed below.

Claim 18 has been replaced with the following replacement claim:

--A method for determining the amount of free gastrin-17 (G17) or gastrin-34 (G34) in a biological fluid sample, comprising the steps of:

(a) obtaining a biological fluid sample comprising a gastrin hormone from a patient;

(b) providing an immobilized antibody selected from the group consisting of an immobilized antibody that selectively binds an N-terminal epitope of G17 and an immobilized antibody that selectively binds an N-terminal epitope of G34;

(c) incubating the sample to allow binding of G17 or G34 in the sample to said antibody to produce an immobilized complex of said antibody bound to the G17 or G34;

(d) washing the immobilized complex to remove unbound antibody, and reacting the complex with a detectable marker-conjugated monoclonal antibody that selectively binds a C-terminal epitope of G17 or G34, to form a detectable marker-conjugated antibody complex;

(e) washing the immobilized detectable marker-conjugated antibody complex, and incubating with a development reagent; and

(f) measuring the developed reagent to determine the amount of free G17 or free G34 in the biological fluid sample;

wherein the monoclonal antibody that selectively binds a C-terminal epitope of G17 or G34 is the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession no. PTA-5896).--

Claim 26 has been replaced with the following replacement claim:

--A method for determining the amount of free G34 in a biological fluid sample, comprising the steps of:

(a) obtaining a biological fluid sample comprising the gastrin hormone G34;

(b) providing an immobilized monoclonal antibody that selectively binds an N-terminal epitope of G34;

(c) incubating the sample to allow binding of the G34 in the sample to said antibody to produce an immobilized complex of said antibody bound to the G34;

(d) washing the immobilized complex to remove unbound antibody, and reacting the complex with a detectable marker-conjugated antibody that selectively binds a C-terminal epitope of G34, to form a detectable marker-conjugated antibody complex;

(e) washing the immobilized detectable marker-conjugated antibody complex, and incubating with a development reagent; and

(f) measuring the developed reagent to determine the amount of free G34 in the biological fluid sample;

wherein the immobilized monoclonal antibody is the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession no. PTA-5893).--

Claim 30 has been replaced with the following replacement claim:

--A method for determining the amount of free Glycine-extended G17 or Glycine-extended G34 in a biological fluid sample, comprising the steps of:

(a) obtaining a biological fluid sample comprising a gastrin hormone from a patient;

(b) providing an immobilized antibody selected from the group consisting of an immobilized antibody that selectively binds an N-terminal epitope of Glycine-extended G17 and an immobilized antibody that selectively binds an N-terminal epitope of Glycine-extended G34;

(c) incubating the sample to allow binding of Glycine-extended G17 or Glycine-extended G34 in the sample to said antibody to produce an immobilized complex of said antibody bound to the Glycine-extended G17 or Glycine-extended G34;

(d) washing the immobilized complex to remove unbound antibody, and reacting the complex with a detectable marker-conjugated monoclonal antibody that selectively binds a C-terminal epitope of Glycine-extended G17 or Glycine-extended G34, to form a detectable marker-conjugated antibody complex;

(e) washing the immobilized detectable marker-conjugated antibody complex, and incubating with a development reagent; and

(f) measuring the developed reagent to determine the amount of free Glycine-extended G17 or Glycine-extended G34 in the biological fluid sample;

wherein the monoclonal antibody is the monoclonal antibody produced by the hybridoma 445-1 (ATCC accession no. PTA-5894) or the monoclonal antibody produced by the hybridoma 445-2 (ATCC accession no. PTA-5895).--

Claim 81 has been replaced with the following replacement claim:

--A method for determining the amount of free Glycine-extended G34 in a biological fluid sample, comprising the steps of:

(a) obtaining a biological fluid sample comprising the gastrin hormone Glycine-extended G34;

(b) providing an immobilized monoclonal antibody that selectively binds an N-terminal epitope of Glycine-extended G34;

(c) incubating the sample to allow binding of the Glycine-extended G34 in the sample to said antibody to produce an immobilized complex of said antibody bound to the Glycine-extended G34;

(d) washing the immobilized complex to remove unbound antibody, and reacting the complex with a detectable marker-conjugated antibody that selectively binds a C-terminal

epitope of Glycine-extended G34, to form a detectable marker-conjugated antibody complex;

(e) washing the immobilized detectable marker-conjugated antibody complex, and incubating with a development reagent; and

(f) measuring the developed reagent to determine the amount of free Glycine-extended G34 in the biological fluid sample;

wherein the immobilized monoclonal antibody is the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession no. PTA-5893).--

New Claims 90-103 have been added as follows:

90. --The method of claim 18, wherein the immobilized antibody of step (b) is a monoclonal antibody.--

91. --The method of claim 90, wherein the immobilized monoclonal antibody selectively binds an N-terminal epitope of G17.--

92. --The method of claim 91, wherein the immobilized monoclonal antibody that selectively binds an N-terminal epitope of G17 is the antibody produced by the hybridoma 400-1 (ATCC accession no. PTA-5889), hybridoma 400-2 (ATCC accession no. PTA-5890), hybridoma 400-3 (ATCC accession no. PTA-5891) or the monoclonal antibody produced by the hybridoma 400-4 (ATCC accession no. PTA-5892).--

93. --The method of claim 90, wherein the monoclonal antibody selectively binds an N-terminal epitope of G34.--

94. --The method of claim 93, wherein the monoclonal antibody that selectively binds an N-terminal epitope of G34 is the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession no. PTA-5893).--

95. --The method of claim 26, wherein the antibody that selectively binds a C-terminal epitope of G34 is a monoclonal antibody.--

96. --The method of claim 95, wherein the monoclonal antibody that selectively binds a C-terminal epitope of G34 is the monoclonal antibody produced by the hybridoma 458-1 (ATCC accession no. PTA-5896).--

97. --The method of claim 30, wherein the immobilized antibody of step (b) is a monoclonal antibody.--

98. --The method of claim 97, wherein the immobilized monoclonal antibody is a monoclonal antibody that selectively binds an N-terminal epitope of Glycine-extended G17.--

99. --The method of claim 98, wherein the immobilized monoclonal antibody that selectively binds an N-terminal epitope of Glycine-extended G17 is the antibody produced by the hybridoma 400-1 (ATCC accession no. PTA-5889), hybridoma 400-2 (ATCC accession no.

PTA-5890), hybridoma 400-3 (ATCC accession no. PTA-5891) or the monoclonal antibody produced by the hybridoma 400-4 (ATCC accession no. PTA-5892).--

100. --The method of claim 97, wherein the immobilized monoclonal antibody is a monoclonal antibody that selectively binds an N-terminal epitope of Glycine-extended G34.--

101. --The method of claim 100, wherein the immobilized monoclonal antibody that selectively binds an N-terminal epitope of Glycine-extended G34 is the monoclonal antibody produced by the hybridoma 401-2 (ATCC accession no. PTA-5893).--

102. --The method of claim 81, wherein the antibody that selectively binds a C-terminal epitope of Glycine-extended G34 is a monoclonal antibody.--

103. --The method of claim 102, wherein the monoclonal antibody that selectively binds a C-terminal epitope of Glycine-extended G34 is the monoclonal antibody produced by the hybridoma 445-1 (ATCC accession no. PTA-5894) or the monoclonal antibody produced by the hybridoma 445-2 (ATCC accession no. PTA-5895).--

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: the prior art fails to teach or suggest a method of determining gastrin hormone using the monoclonal antibodies produced hybridomas 458-1 (ATCC Accession No. PTA-5896), 401-2 (ATCC PTA-5893), 445-1 (ATCC PTA-5894), or 445-2 (ATCC PTA-5895).

3. It is noted that the specification has been amended as above in order to provide antecedent basis for the selectivities of the antibodies, which were present in the claims as originally filed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christine Foster, Ph.D.
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600